Witness Name:Alex Sienkiewicz Statement No.:WITN5746001 Exhibits: WITN5746002-008 Dated: 30.09.21

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF ALEX SIENKIEWICZ

I, Alex Sienkiewicz, of Public Health England, Porton Down, Manor Farm Road, Porton Down, Salisbury, SP4 0JG will state as follows:

1. I am a Senior Civil Servant and Director of Public Health England ("PHE") Porton Down and Director of Corporate Affairs for PHE. I joined PHE when it was established in shadow form in 2012 as part of the health and social care reforms enacted that year, initially as Chief of Staff. PHE was formally established on 1 April 2013 from 70 plus predecessor organisations, the most significant of which was the Health Protection Agency, which formerly had responsibility for what is now the PHE Porton Down site. I began my career in the Civil Service in 1999, subsequently joining the NHS in 2007, where I held a Director role in an acute teaching hospital until 2012, when I re-joined the Civil Service. On 1 October 2021, the health protection functions of PHE, including Porton Down, transfer to the UK Health Security Agency ("UKHSA"), an Executive Agency of the Department of Health and Social Care. My responsibility for Porton Down ceases as of midnight on 30 September 2021, with the UKHSA Chief Scientific Adviser assuming full responsibility for the Porton Down site. Any new queries following this point should be addressed to the UKHSA Chief Scientific Adviser in the first instance.

2. Save where otherwise stated, all facts and matters referred to in this witness statement are true and within my own knowledge and have come to my attention during the course of my work. Insofar as facts and matters are not directly within my knowledge, they are true to the best of my knowledge and belief. I am duly authorised to make this statement on behalf of PHE Porton Down.

The Purpose of this Witness Statement

- I make this witness statement in response to two requests from the Infected Blood Inquiry ("IBI") under Rule 9 of the Inquiry Rules 2006 ("R9") dated 10 March 2020. Annex A (WITN5746002) of this witness statement responds to a further R9 request dated 11 June 2021.¹
- 4. A document setting out the methodology Porton Down has used to respond to the two initial R9 requests is attached as Appendix 1 (WITN5746003). The first request of 10 March 2020 asked 6 questions. I will address each question in turn. The second request of 10 March 2020 asked for a schedule of documents, which I attach to this statement as Appendix 2 (WITN5746004).
- The third request of 11 June 2021 asked 21 additional questions in relation to the draft response and appendices to the first and second request of 10 March 2021. I include responses to these questions at Annex A (WITN5746002).

PHE Porton Down

6. PHE is an operationally autonomous executive agency of the Department of Health and Social Care. It exists to protect and improve the nation's health and wellbeing, and to reduce health inequalities. Porton Down is an area of downland to the northeast of the village of Porton, Salisbury. It is the location of three principal organisations: the Government's Defence Science & Technology Laboratories, part of the Ministry of Defence; Wiltshire Council's Porton Science

¹ The deadlines for responding to the 10 March 2020 Rule 9 requests and the 11 June 2021 Rule 9 request were extended until 30 October 2020 and 30 September 2021 respectively, due to PHE Porton Down's involvement in responding to the Covid-19 pandemic.

Park; and Public Health England Porton Down, part of the Department of Health and Social Care.

- 7. PHE Porton Down is a microbiological establishment,² comprising one of the largest UK capabilities for the handling of dangerous human pathogens and animal modelling of infectious diseases. One of its key functions is to understand pathogenesis and undertake pre-clinical development and assessment of new vaccines and therapeutic products.
- 8. The capability is also used to undertake studies in microbiological aerobiology, decontamination and detection, and to develop diagnostic assays for clinical use. High priority activities include the study of the causative agents of disease, including (for example) of the dangerous pathogens Ebola, Zika, Crimean Congo Haemorrhagic Fever, Q Fever, anthrax, influenza, and many others.
- 9. PHE Porton Down also specialises in the diagnosis and management of unusual or hazardous infectious diseases present in the UK or imported into the country and provides a clinical service through its Rare and Imported Pathogens Laboratory. It is also home to the South West Cancer Registry and the Food, Water and Environment Laboratory for the South of England. With the exception of the Cancer Registry, which transfers to NHS Digital, all of these functions will transfer to UKHSA on 1 October 2021.
- 10. In addition to the above operational activities, the site hosts various support functions and soft services. Locally, there include activities such as facilities management, estates and engineering services; nationally the site is also home to PHE's finance department.

R9 – 10 March 2020.

Question 1 – Please confirm your response to Dr Phin's email dated 17 December 2018 (see Attachment 1), and specify what, if anything, was provided by PHE Porton to Dr Phin and his team.

² PHE Porton Down's function has always been focused on the study of microorganisms. Appendix 3 (as described below) provides more detail.

11. Dr Phin's email of 17 December 2018 specifically drew attention to the Centre for Applied Microbiology and Research ("CAMR") departments at Porton Down. On receipt of this email, verbal enquiries were made with senior managers on the site. As the work of CAMR was largely around development of an animal model for HIV, understanding pathogenesis and assessment of candidate therapeutics, it was not thought that it would hold any documents relevant to the IBI's Terms of Reference. Dr Neil Woodford, a member of PHE's National Infection Service, responded to Dr Phin on 19 December 2018 to explain this, and his email together with a list of publications he appended are attached to this witness statement as Appendix 4 (WITN5746006). For the avoidance of all doubt, provision of this email is to assist the Inquiry and to respond to Question 1 above as fully as possible: it is not a waiver or limited waiver of legal professional privilege.

Question 2 – Please confirm the methodology and approach used by your team at PHE Porton to perform the searches necessary in order to respond to Dr Phin's email.

12. As above, verbal enquiries were initially made in response to Dr Phin's email. On receipt of the Inquiry's more detailed R9 requests directed to PHE Porton Down, PHE Porton Down has undertaken systematic searches. The methodology and approach employed are set out in the document attached as Appendix 1 (WITN5746003) entitled "Scope and Methodology for PHE Porton Down".

Question 3 – Please provide a complete account of the PHE Porton archives and repositories likely to contain the search terms specified at paragraphs 13 and 14 of Dr Phin's statement to the Inquiry dated 20 December 2019 (see Attachment 2), including those storing documents and information in hard copy, electronic format and any other form. In particular:

a. Please confirm whether documents and data relating to the following entities are contained in the PHE Porton archives, and if so, for which periods:

(i) Microbiological Research Establishment;

- (ii) Microbiological Research Authority;
- (iii) Centre for Applied Microbiology and Research (CAMR);

(iv) Public Health Laboratory Service, in particular from Oxford, Manchester and Bristol;

- (v) Epidemiological Research Establishment;
- (vi) Epidemiological Research Laboratory;
- (vii) Communicable Disease Surveillance Centre;

(viii) Documents from the Directors of Public Health and Consultants in Communicable Disease Control;

- (ix) Blood Transfusion Service;
- (x) Blood Products Laboratory;

(xi) any other working groups, committees, or subcommittees you consider relevant to the Inquiry's Terms of Reference.

- 13. In order to aid understanding of the nature and ownership of PHE Porton Down over time and the documents held, I attach as Appendix 3 (WITN5746005), a document entitled "Organisational structure and records held at PHE Porton Down" which has been prepared by Dr Peter Hammond, Deputy Director of PHE Porton Down and Deputy Director of Corporate Affairs, who has worked at Porton Down since 1977. This document also contains supplementary notes which address matters which may assist the Inquiry.
- PHE Porton Down holds potentially relevant documentation belonging only to (ii) and (iii) in the list set out within Question 3a above and in the R9 request dated 10 March 2020. A low threshold test for relevance has been applied, as explained in Appendix 1 (WITN5746003).

Question 4 – Please describe CAMR's function in relation to research into: The hepatitis B virus; The hepatitis C virus; HIV; vCJD; and/or Other blood-borne diseases.

- 15. CAMR was primarily a healthcare research organisation. For example, its remit in 1987³ was:
 - 1. serving PHLS needs, for example in reference facilities for special pathogens
 - 2. serving broader DHSS interests such as meningitis research and developing a new pertussis vaccine
 - 3. biotechnology work for British industry
 - 4. income generation by various channels, including [CAMR's] partnership with Porton International Limited

The statutory functions of the MRA when it was created in 1994⁴ were:

- 1. provide such advice and assistance as may be required by bodies exercising functions on behalf of the Crown for the protection of persons against microbiological hazards
- 2. to conduct research and development with a view to maintaining and enhancing technological capacity to provide that advice and assistance.

Summary of HIV-1 research being undertaken at CAMR in 1987-1992

Research on HIV in the 1980s related to the following:⁵

1. Bulk production of HIV antigen for diagnostic tests produced by

³ Letter, Baroness Trumpington [Joint Parliamentary Under Secretary of State], to Dr CE Gordon Smith [Chairman, PHLS Board]. Undated, but date-stamped 17 March 1987, copy attached as Appendix 5 (WITN5746007).

⁴Microbiological Research Authority (Establishment and Constitution) Order (SI 1994/603).

⁵This information was taken from a letter from Dr Peter Sutton (Director of CAMR) to Prof Alan Glynn (Director of CPHL), dated 1 July 1987 (DIR/125), copy attached as Appendix 6 (WITN5746008).

Wellcome Diagnostics

- 2. Collaborative study on mother-to-child transmission
- 3. Study of antiviral compounds
- 4. Models
- 5. Study of molecular biology of HIV and cloning of gene products
- 6. Ultrastructural studies of HIV using electron microscopy

Summary of HIV-1 research undertaken at Porton since 1993

(Appendix 2 Schedule of Documents Page 9 Sub-departmental assessment)

- 16. The AIDS vaccine research programme involved the establishment of an animal model of AIDS (SIV-macaques) to investigate the efficacy of vaccine approaches. This programme did not involve the use of human blood or blood products.
- 17. Studies of HIV isolates from Ugandan patients involved serology studies to investigate the variation in HIV gene expression in different isolates. This work did not involve the use of UK human blood or blood products but did involve the study of blood from Ugandan HIV patients.

Summary of HCV research undertaken at Porton

(Appendix 2 Schedule of Documents Page 8 Sub-departmental assessment)

18. A small research project was undertaken between 1996 and 1998 to investigate molecular techniques to determine an efficient and reliable method for genotyping clinical isolates of Hepatitis C virus, to allow more informed decisions to be made with regards to therapy and prognosis. HCV positive sera of known genotypes were provided by Bristol Public Health Laboratory and Hong Kong PHL to support these studies. The project was short-lived, indicating that the approach was not pursued. 19. A small research project was undertaken in 2005 with the aim of developing a method for the oral diagnosis of HCV infection. This project used positive control materials provided by colleagues at the Centre for Infections, Colindale. The project did not progress for long, indicating that the approach was not pursued.

Summary of TSE research undertaken at Porton

(Appendix 2 [WITN5746004] Schedule of Documents Page 11 Subdepartmental assessment)

20. Between 1998 and 2015 the Technology Development Group at Porton (as part of CAMR, HPA and PHE) carried out a variety of research projects regarding Transmissible Spongiform Encephalopathies (specifically Scrapie and vCJD). These projects were mostly concerned with the detection of prions in various tissues, on surgical instruments etc. and with the decontamination and/or removal of prions from instruments.

Summary of HBV research undertaken at Porton

21. Small projects in 1999 and 2005 looked at expression of HBV polymerase by baculovirus, with associated assays.

Question 5 – Please describe the management structure of CAMR from 1970 - 2000 and state if it differs to our understanding in the attached Organogram of PHE entities (See Attachment 3).

22. In order to aid understanding of the nature and ownership of PHE Porton Down over time and the documents held, I attach at Appendix 3 (WITN5746005), a document entitled "Organisational structure and records held at PHE Porton Down". This document also contains supplementary notes which address matters which may assist the Inquiry.

- 23. In relation to the box of the Organogram for CAMR, our understanding is that after HPA, as successor to CAMR, transferred to PHE in 2013, it did not become Porton Biopharma Limited. Porton Biopharma Limited (line vi) was created out of the manufacturing department at PHE Porton Down as a separate entity on 1 April 2015 as a limited liability company wholly owned by the Secretary of State for Health, while PHE Porton Down continued to exist as a centre. The major component of the latter was the National Infection Service (line vii), but other departments were (and are) located at PHE Porton Down too.
- 24. In relation to the box for the National Radiological Protection Board, this indicates that it joined PHE in 2012. This would not have been possible as PHE did not exist until 2013. In any event, NRPB itself did not exist in 2012, as its functions transferred into, and were subsumed by, the HPA in April 2005.
- 25. I am not able to comment upon all of the bodies not related to Porton Down. If there are queries about these, they should be directed to the Department of Health and Social Care, which was and is responsible for the transition into the HPA, and from the HPA into PHE, and the impending transition from PHE into UKHSA.

Question 6 – Please confirm the government ministers, and individuals at the Department of Health Social Services, that

- (i) Microbiological Research Establishment
- (ii) Microbiological Research Authority and
- (iii) CAMR

reported their findings to on research on those diseases listed in 4) above.

26. The Microbiological Research Establishment was a part of the Ministry of Defence. It did not (ever) report to the Department of Health & Social Security. Any questions from the Inquiry relating to the records of MRE should be directed to the Ministry of Defence and/or the National Archives.

- 27. The Centre for Applied Microbiology & Research (CAMR) was part of PHLS on its creation in 1979, and then a part of the Microbiological Research Authority (MRA) from 1994-2003. The MRA was the legal entity and CAMR was its operational body; notwithstanding that distinction, they were not two different organisations. Therefore, PHE Porton Down considers that the relevant organisations referred to in Question 6 are more accurately:
 - (i) Microbiological Research Establishment (MOD)
 - (ii) CAMR under the PHLS (DHSS)
 - (iii) CAMR as part of the MRA (DHSS/DH)⁶
- 28. The Secretary of State for Health/Health and Social security from time to time was ultimately responsible for (ii) and (iii) above. However, it would be exceptional for these bodies to report their findings directly to the Secretary of State as the latter would discharge their duty through various officials at various levels. In practice, reports would usually be made to the sponsoring branch or policy branch for the relevant area of work and PHE Porton Down holds no central list of officials working beneath Ministers.
- 29. The names of Ministers are a matter of public record. In order to assist the Inquiry as far as possible, PHE Porton Down has compiled the following:

Ministers (Secretaries of State for Health) during the time of the above establishments, 1976 to date

David Ennals	08 April 1976	04 May 1979
Patrick Jenkin	05 May 1979	14 September 1981
Norman Fowler	14 September 1981	13 June 1987
John Moore	13 June 1987	25 July 1988
Kenneth Clarke	25 July 1988	02 November 1990

⁶ See also From Biological Warfare to Healthcare. ISBN: 0-333-75383-6.

William Waldegrave	02 November 1990	10 April 1992
Virginia Bottomley	10 April 1992	05 July 1995
Stephen Dorrell	05 July 1995	02 May 1997
Frank Dobson	03 May 1997	11 October 1999
Alan Milburn	11 October 1999	13 June 2003
John Reid	13 June 2003	06 May 2005
Patricia Hewitt	06 May 2005	27 June 2007
Alan Johnson	28 June 2007	05 June 2009
Andy Burnham	05 June 2009	11 May 2010
Andrew Lansley	11 May 2010	04 September 2012
Jeremy Hunt	04 September 2012	09 July 2018
Matt Hancock	09 July 2018	26 June 2021
Sajid Javid	26 June 2021	Incumbent

Request for the production of specified documents and information under Rule 9(2) of the Inquiry Rules 2006 – 10 March 2020

- 30. In response to the above R9 request, please find attached, at Appendix 2 (WITN5746004), a schedule of documents
- 31. It is intended that this Witness Statement, together with the Appendices (WITN5746003-008) and Annex A (WITN5746002), will provide the Inquiry with a comprehensive explanation of the work undertaken at PHE Porton Down in the past and the nature of documents held. PHE Porton Down, and subsequently UKHSA Porton Down as of 1 October 2021, are committed to assisting the Inquiry in whatever way they are able to do so and are grateful to the Inquiry for allowing an extension of time to respond to the Rule 9 requests in light of Porton Down's considerable involvement in the ongoing response to the COVID-19 pandemic.

Statement of Truth

I believe that the facts stated in this witness statement are true.

GRO-C

Alex Sienkiewicz 30 September 2021

INFECTED BLOOD INQUIRY

INDEX OF DISCLOSURE DOCUMENTS RELEVANT TO ALEX SIENKIEWICZ WITNESS STATEMENT

	Description	Document ID
1.	Annex A – Response to a request for a written statement under Rule 9 of the Inquiry Rules 2006 – 11 June 2021.	WITN5746002
2.	Appendix 1 - Scope and Methodology for PHE Porton Down	WITN5746003
3.	Appendix 2 - Schedule of Documents	WITN5746004
4.	Appendix 3 - Organisational Structure and Records Held at PHE Porton Down	WITN5746005
5.	Appendix 4 - Letter from Dr Neil Woodford to Dr Phin - 19 December 2018	WITN5746006
6.	Appendix 5 - Letter from Baroness Trumpington to Dr CE Gordon Smith (Chairman, PHLS Board). Date stamped 17th March 1987	WITN5746006
7.	Appendix 6 - Letter from Dr Peter Sutton (Director of CAMR) to Professor Alan Glynn (Director of CPHL) dated 1 July 1987 (DIR/125)	WITN5746008